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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/636,801	08/10/00	MITCHAM J	210121.462C4

EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1631	10

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JANE E R. POTTER
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVENUE
STE 6300
SEATTLE WA 98104-7092

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copies

Office Action Summary	Application No.	Applicant(s)	
	09/636,801	MITCHAM ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *3-8,13-20,22,25-68 and 70-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9-12,21,23,24 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 August 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of Group I, claims 1, 2, 9-12, 21, 23, 24 and 69-72, and SEQ 392 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3-8, 13-20, 22, 25-68 and all other sequences are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Claims 70, 71 and 72 are withdrawn from consideration as being drawn to a non-elected invention as they read on non-elected sequences.

Applicant is requested to cancel non-elected claims, and further to amend the claims to reflect the elected invention, SEQ ID NO: 392.

Claims 1, 2, 9-12, 21, 23, 24, and 69 are examined herein.

Priority

This application is a continuation-in-part of several applications. No protein sequences were disclosed in 09/215, 681 and 09/216,003. Priority to those applications is denied. A comparison of the elected sequence 392 with the CRF of 09/338,933 finds no comparable protein. Priority to this application is denied. The first application to disclose SEQ: 392 is parent application 09/404,879. Priority is granted to 9/24/1999, the filing date of 09/404,879.

Information Disclosure Statement

The IDS filed 10/16/00 has been entered and considered. An initialed copy of the form PTO-1449 is enclosed with this action.

Drawings

Applicant is required to submit a proposed drawing correction in reply to this Office action. Due to changes in Office procedure, formal correction of the noted defect **can no longer be deferred** until the application is allowed by the examiner.

Specifically, the type in the figures disclosing sequences is faint, and blurry. Figures 11-14 are unreadable. Margins are improper, and the type is too small on all figures.

Specification

The disclosure is objected to because of the following informalities: The brief description of the drawings does not refer to each panel of each figure specifically (Figure 1, Figure 15, etc.). Further, the brief description of Figures 11-14 should be amended to reflect that the figure is a chart, to clearly identify the disclosed material. For example, "Figure 11 is a chart which depicts...".

Further, the Table beginning at page 50 is not properly labeled as a table. It would appear it should be labeled Table 1.

Appropriate correction is required.

35 U.S.C. 101/112 Utility Rejections

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility:

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1, 2, 9-12, 21, 23, 24, and 69 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The claims are drawn to isolated polypeptides having part or all of SEQ ID NO: 392. The asserted utilities set forth in the specification include use in a diagnostic assay for ovarian or breast cancer, and in the prevention and/or treatment of breast or ovarian cancer. The table beginning at page 50 does not identify SEQ ID NO: 392 as a polypeptide that is specifically expressed in ovarian tumor cells.

At page 53, after the end of the table, SEQ ID NO: 392 is identified as being a form of a predicted protein from an internal clone designation and the protein sequence is designated O8E. SEQ ID NO: 392 is further defined as the "b" form of O8E, having additional sequences when compared to another (non-elected) sequence. The predicted amino acid sequence was determined by computer analysis. The designation of "O8E" does not appear to be an art-recognized designation for known proteins such that their designation could impart any well-established uses for the claimed polypeptide.

There is no other particular identifying information associated with SEQ ID NO: 392. The specification does not list any potentially homologous prior art sequences. At page 54, various 20-mers of O8E sequence were used in order to produce O8E polyclonal antibodies. The specification does not identify whether SEQ: 392 was used to generate the 20-mers for the generation of the polyclonal antibodies, or whether it was SEQ ID NO: 394- the non-elected

sequence. The specification sets forth at page 54, line 11, only that "peptides corresponding to the O8E protein were synthesized."

The polyclonal antibodies induced by these subfragments of an O8E protein were used for immunohistochemistry testing of ovarian cancer tissue samples (specification, p 54). Only 1 out of 6 samples was positive for an O8E antibody epitope. No control results are disclosed. It is unclear from this experiment whether the antigen or epitope could also be present in normal tissue sections, or other tissues in the body. Also, it is unclear if the 6 samples selected to test were representative of all types of ovarian cancer, such that the relevance of the one positive sample can be determined.

Example 5 of the specification, starting at the bottom of page 55, sets forth that "Potential HLA-A2 binding epitopes of O8E were predicted by using the full length open reading frame (ORF) from O8E..." and does not clearly set forth whether the elected SEQ: 392 or another non-elected sequence, such as SEQ: 394 was used, nor whether any of the predicted peptides *had* any HLA-A2 binding activity.

Examples 6 and 7 of the specification detail a FACS sorting analysis of a breast cancer cell line, a positive control cell line expressing O8E, and "MB415" cells, which are not clearly identified. Presumably, this is a negative control cell line, but its characteristics are not disclosed. No conclusions are drawn between the results of this assay on established cell lines, and any clinically relevant samples. While one type of breast cancer cell line may be positive for O8E expression, an immortalized cell line does not completely mimic the behaviour of a cancerous cell *in vivo*. Further, there are many stages of breast cancer, such that the characteristics of the cell line may not reflect all the relevant stages, such as neoplasia, malignant metastatic, necrotic. As many types of breast cancer exist (ductal, lobular carcinoma, mucinous carcinoma etc.) clearly more testing would need to occur to determine whether or not the O8E antigen is useful in the detection of breast cancer.

Given the disclosure of the specification, one of ordinary skill in the art would have to perform additional tests to determine whether O8E is an antigen that is diagnostic for ovarian cancer or breast cancer, or whether the O8E protein would have an effects when administered in vivo..

In regards to the asserted utility in the prevention or treatment of breast or ovarian cancer, the specification does not disclose any data or experiments showing that the administration of SEQ: 392, or any of its sub-peptides, have any effect on the development of breast or ovarian cancer, nor does the specification disclose any information or data supporting that administration of SEQ: 392 has any effect on the course of breast or ovarian cancer. At no point are the *in vivo* properties, activities or effects of the O8E protein discussed. The O8E protein appears to be completely novel such that there is no body of art to rely on for enabling information and data. No conclusions are drawn between the results of the FACS assays on established cell lines, and any clinically relevant samples. Clearly more testing would need to occur to determine whether or not the O8E antigen is useful in the detection of those cancers, let alone the treatment thereof.

The art of cancer therapy recognizes that not all "cancer" antigens are useful in the treatment or alleviation of cancers. For example, Gillespie et al. (1998, PTO-1449) discusses how MAGE antigens were also found in normal tissue, leading to questions about previous assumptions of MAGE's role in carcinogenesis. Bookman (1998 PTO-1449) discusses the future of biological therapies of cancer, and details the great amounts of research necessary before a biological reagent such as an antibody or polypeptide can be used.

Given the disclosure of the specification, one of ordinary skill in the art would have to perform additional tests to determine whether O8E is an antigen that is diagnostic for ovarian cancer or breast cancer, or whether the O8E protein would have an effects when administered in vivo..

The need for such further research and experimentation clearly indicates that the asserted utilities for the claimed polypeptides are not disclosed and therefore are not specific, substantial and credible utilities Further no well established utility is supported for any one polypeptide. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record

discloses or suggests any property or activity for the claimed polypeptides such that another non-asserted utility would be well-established for the compounds.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claim(s) 1, 2, 9-12, 21, 23, 24, and 69 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

Claims 1, 2 and claims 9-12, 21, 23 and 24 dependent therefrom, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

Claim 1 recites that the portion or variant of SEQ: 392 is able to bind an antibody with specificity to the polypeptide encoded by SEQ: 391, which is SEQ ID NO: 392. The specification, as filed, does not identify which portions of the polypeptide of SEQ ID NO: 392 would be likely to have antigenic sites such that they could bind to an antibody specific for SEQ ID NO: 392. The specification does not provide such an antibody that is specific to SEQ ID NO: 392. The identification of antigenic sites in a polypeptide sequence is not 100% predictable, nor is it clear that any particular predicted antigenic site would bind to an antibody specific to the whole polypeptide sequence. While working examples are not, per se, required in the specification, the disclosure must provide enough information for one of skill in the art to be able to practice the invention as it is now claimed, without undue experimentation. While the skill in the art of immunology and peptide science is high, the identification of antigenicity and binding to antibodies is unpredictable, and one of ordinary skill in the art would be required to perform undue experimentation on the predicted polypeptide sequence to identify polypeptides having at

least 20 contiguous amino acids, and which also bind to an antibody specific for the whole polypeptide.

Claims 9-12, 23, 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims are drawn to pharmaceutical compositions, and vaccine compositions. The specification, as filed, is not enabling for these compositions.

MPEP 2164.01(c) states:

> When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use.

For the above rejected claims to be enabled, the specification must teach how to make the claimed composition without undue experimentation and must teach how to use the composition for at least one pharmaceutical use without undue experimentation. The following are examples of "pharmaceutical uses": administering vitamin supplements (preventing disease); using labeled antibodies for in vivo imaging (diagnosing disease); administering a substance to alleviate a symptom of a disease (alleviating or treating disease); and administering an antibiotic (curing bacterial infection). However, a use of an antigenic substance administered to an animal to produce antibodies wherein the resultant antibodies are intended to be collected from the animal and used in various ways, e.g., in an assay system or in passive immunization, is not a pharmaceutical use. In the example of an antigenic substance being used to generate antibodies for use in another assay or procedure, the antigenic substance is not being used to prevent, diagnose, alleviate, treat, or cure a disease in the animal to which the antigenic substance was administered. The animal is merely being used as a bioreactor to make the antibodies that will ultimately be used, maybe even in the prevention, diagnosis, alleviation, treatment, or cure a disease in another animal. Thus, to enable a pharmaceutical use for a substance, the specification must teach how to use the substance, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure a disease in the animal to which the substance is administered.

In the instant application the claims are drawn to "A pharmaceutical composition comprising SEQ: 392" and "A vaccine comprising SEQ ID NO: 392." The pharmaceutical use for these compositions is identified in the specification as being to prevent or treat breast and/or ovarian cancer. This pharmaceutical use is not enabled by the specification as filed.

The specification does not disclose any data or experiments showing that the administration of SEQ: 392, or any of its sub-peptides, have any effect on the development of breast or ovarian cancer, nor does the specification disclose any information or data supporting that administration of SEQ: 392 has any effect on the course of breast or ovarian cancer. At no point are the in vivo properties of the O8E protein discussed such that one of skill in the art would be able to practice the above recited pharmaceutical uses without undue experimentation. While working examples are not, per se, required, the specification must provide ample guidance for one of skill in the art to practice the invention. The O8E protein appears to be completely novel such that there is no body of art to rely on for enabling information and data. As set forth previously, polyclonal antibodies were used for immunohistochemistry testing using ovarian cancer tissue samples (specification, p 5) however only 1 out of 6 samples was positive for an O8E antibody epitope. Examples 6 and 7 of the specification detail a FACS sorting analysis of a breast cancer cell line, a positive control cell line expressing O8E, and "MB415" cells, which are not identified. Presumably this is a negative control cell line, but its characteristics are not disclosed. No conclusions are drawn between the results of this assay on established cell lines, and any clinically relevant samples. While one type of breast cancer cell line may be positive for O8E expression, an immortalized cell line does not completely mimic the behaviour of a cell in vivo. As many types of ovarian cancer, and breast cancer (ductal, lobular carcinoma, mucinous carcinoma etc.) exist, clearly more testing would need to occur to determine whether or not the O8E antigen is useful in the detection of those cancers, let alone the treatment thereof.

The art of cancer therapy recognizes that not all "cancer" antigens are useful in the treatment or alleviation of cancers. For example, Gillespie et al. (1998, PTO-1449) discusses how MAGE antigens were also found in normal tissue, leading to questions about previous assumptions of MAGE's role in carcinogenesis. Bookman (1998 PTO-1449) discusses the future of biological therapies of cancer, and details the great amounts of research necessary before a biological reagent such as an antibody or polypeptide can be used.

Given the disclosure of the specification, one of ordinary skill in the art would have to perform additional tests to determine whether O8E is an antigen that is diagnostic for ovarian cancer or breast cancer, or whether the O8E protein would have an effects when administered in vivo.. Note, this rejection could be overcome by deleting the word "pharmaceutical" or "vaccine" from the claim.

Claims 1, 2, 9-12, 21, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 392 which corresponds to the "b form" of a protein designated O8E in the specification. The claims are directed to encompass immunogenic portions, immunogenic variants thereof, mutated sequences, allelic variants, substitutions, deletions, insertions, and additions to SEQ 392, and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 392, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The protein or nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found

unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

The specification does not set forth any of these definitions for other polypeptides which fall within the scope of the claims. An applicant may also show written description of an invention by combining a partial structure, physical properties, or chemical characteristics with a known or disclosed specific function. However, no specific function or activity had been ascribed to any one elected sequence in the specification, as filed.

The written description requirement for any claim drawn to a genus can be met through sufficient description of a representative number of species within the genus. The broadest claim for the elected polypeptide is a separate genus. The specification, as filed, only discloses the single species of SEQ: 392, which is not sufficient to support the assertion that Applicant was in possession of the entire genus being claimed.

Therefore, claims drawn to purified polypeptides comprising SEQ: 392, but not the full breadth of the claims, would meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Conclusion

No claim is allowed.

The full length polypeptide appears to be free of the prior art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 99/63088 (Genentech, 9 December 1999) discloses a polypeptide sequence identical to SEQ ID NO: 392 from 28-309. This application appears to have priority as early as June 1998. As this reference is over 800 pages long, only the relevant page (Fig 208) disclosing the sequence is provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can generally be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

The official fax number for this Art Unit is (703) 308-4242. An unofficial fax number, direct to the Examiner is 703 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524.

mkz
8/14/01

MARY K. ZEMAN
PATENT EXAMINER
AU 1631

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.